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DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES
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PRESS RELEASE

#2012 – 008

Recall of Certain Over-The-Counter Products Due to Potential Presence of Foreign Tablets or Chipped or Broken Tablets or Gelcaps

The Department of Public Health and Social Services, in coordination with the U.S. Food and Drug Administration (FDA) and Novartis Consumer Health, Inc. (NCH), would like to inform the public of a voluntary recall involving all lots of select bottle packaging configurations of Excedrin® and NoDoz® products with expiry dates of December 20, 2014 or earlier as well as Bufferin® and Gas-X Prevention® products with expiry dates of December 20, 2013 or earlier, in the United States. NCH is taking this action as a precautionary measure because the products may contain stray tablets, capsules, or caplets from other Novartis products, or contain broken or chipped tablets. These over-the-counter products were distributed nationwide to wholesalers and retailers.

Mixing of different products in the same bottle could result in consumers taking the incorrect product and receiving a higher or lower strength than intended or receiving an unintended ingredient. This could potentially result in overdose, interaction with other medications a consumer may be taking or an allergic reaction if the consumer is allergic to the unintended ingredient. NCH is not aware of adverse events reported with the issues leading to the recall.

Novartis Consumer Health Inc. is notifying its distributors and customers and is arranging for return of all recalled products. Wholesalers and retailers should stop distribution and return the affected product using Novartis Product Return information that is being provided to them.

Consumers that have the affected commodity should stop using the product(s) and contact the Novartis Consumer Relationship Center at 1-888-477-2403 (available Monday-Friday 9 a.m. to 8 p.m. Eastern Time) for information on how to return the affected products and receive a full refund. For more detailed information, consumers should visit the NCH website at www.novartisOTC.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these drug products.

Adverse events that may be related to the use of these products may be reported to FDA's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax:

- Online: www.fda.gov/medwatch/report.htm
- Regular Mail: Use postage-paid FDA form 3500 available via the website, www.fda.gov/MedWatch/getforms.htm, then mail to MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178

To date, the Division of Environmental Health of this Department has determined that the implicated products were available at Island Fresh IGA Supermarket (Chalan Pago) and all Pay-Less Supermarkets (Agana, Dededo, Micronesia Mall, Mangilao, Oka, Sinajana and Yigo locations). Corrective actions were taken immediately at these retail stores.

The Department has not received any local reports of injuries or illnesses associated with the consumption of these recalled commodities. Consumers who have purchased any of the implicated products listed above are urged to stop using the product immediately and should return it to the place of purchase.

For any questions, please contact the Division of Environmental Health at 735-7221.

JAMES W. GILLAN
Director

Attachment